

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

United States of America
ex rel. John Doe,

Plaintiff-Relator

v.

William Thomas Odom, II, M.D.

Defendant.

C/A No. 3:20-cv-00803-CMC

Order

This civil action is before the court on motion of Defendant William Thomas Odom, II (“Odom”) to dismiss all claims asserted against him pursuant to Rules 8(a)(2), 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure and 31 U.S.C. § 3730(e)(4). ECF No. 18. As part of this motion, Odom also seeks attorneys’ fees and costs on the ground the allegations in the Complaint are clearly frivolous. *Id.* at 24. Plaintiff-Relator John Doe (“Relator”) filed an opposition, ECF No. 26, and Odom replied, ECF No. 27. This action is also before the court on Odom’s supplemental motion to dismiss all claims asserted against him pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure and 31 U.S.C. § 3730(e)(3). ECF No. 38. As part of this motion, Odom again seeks attorneys’ fees and costs. Relator filed an opposition, ECF No. 39, and Odom replied, ECF No. 40. For the reasons set forth below, the court denies Odom’s motion to dismiss in part, grants it in part, ECF No. 18, denies in full Odom’s supplemental motion to dismiss, ECF No. 38, and denies in full his requests in both motions for attorneys’ fees and costs.

I. BACKGROUND

A. Procedural History.

1. The Complaint.

Relator initiated this action in February 2020, seeking recovery on behalf of the United States of America (“the Government”) for alleged violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (“the FCA”). As relevant here, the FCA imposes civil liability on “any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . .” to the Government. 31 U.S.C. § 3729(a)(1)(A). Additionally, the FCA imposes civil liability on “any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . .” for payment by the Government. *Id.* at § 3729(a)(1)(B).

In the Complaint, Relator alleges Medicare provider Odom, a board certified anesthesiologist, violated each of these statutory provisions by knowingly submitting or causing submission of thousands of claims to the Government for reimbursement of medically unnecessary medical services he allegedly performed in years 2014 through 2017. ECF No. 1 at 16-17 (Count I—alleging violation of § 3729(a)(1)(A)), 17 (Count II—alleging violation of § 3729(a)(1)(B)). In general, the Complaint alleges Odom knowingly submitted or caused submission of false claims for Medicare reimbursement of nerve block injections performed in years 2016 and 2017 under Current Procedural Terminology Code (“CPT Code”) 64450, ultrasonic guidance imaging performed in 2014, 2015, 2016, and 2017 under CPT Code 76492, and nerve transmission studies performed in 2016 under CPT Code 95909.

As required by the FCA, the matter was initially maintained under seal to allow the Government to investigate the claims alleged and elect whether to intervene. 31 U.S.C. § 3730(b)(2). On May 22, 2020, the Government declined intervention. *Id.* § 3730(b)(4); ECF No.

10. The court then ordered the seal lifted on all documents in the case, thus allowing for service of process on Odom. 31 U.S.C. § 3730(b)(2), (4); ECF No. 11.

2. Initial Motion to Dismiss.

On June 19, 2020, Odom filed his initial motion to dismiss (Initial Motion to Dismiss) under Rules 8(a)(2), 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure and the FCA's public-disclosure bar, 31 U.S.C. § 3730(e)(4). ECF No. 18. Odom states he is board certified in anesthesiology and is a Principal Investigator in a study to "demonstrate the non-inferiority of devices in question (Axon II 250 Hz small pain fiber (spf) testing device, Anodyne/MIRE, TENS, NBPM (Nerve Block pain management) for lower extremity neurological ischemia." *Id.* at 6. He argues this explains his high volume of certain medical claims. Further, he contends this entire action should be rendered moot because he and his medical practice are "already experiencing collection activity for the same services referenced in Relator's complaint." *Id.* at 7. According to Odom, the current action "attempts to duplicate the government's current collection efforts." *Id.* Odom further asserts this case should be dismissed pursuant to the FCA's public-disclosure bar, which, in general, is triggered when the fraud allegations existed in the public domain before a *qui tam* relator filed suit, and Relator fails to satisfy the original source exception to overcome this bar. *Id.* at 7-8. Finally, Odom asserts Relator fails to plead his allegations of fraud with sufficient particularity to satisfy Rule 9(b) of the Federal Rules of Civil Procedure ("Rule 9(b)") and fails to allege facts which, if accepted as true, state a claim to relief that is plausible on its face as required by Rule 8(a)(2) of the Federal Rules of Civil Procedure ("Rule 8(a)(2)").

Relator responded in opposition, arguing repayment of alleged false claims might reduce but would not eliminate Odom’s liability in this case, as the FCA provides for treble damages and civil penalties.¹ 31 U.S.C. § 3729(a); ECF No. 26 at 3. Relator also contends the FCA’s public-disclosure bar does not apply, as (1) certain documents were not publicly available and (2) data published by the Centers for Medicare and Medicaid Services (“CMS”) does not constitute a public disclosure as it would not have put the Government on notice of Odom’s fraud, as Relator “applied his medical knowledge and experience to what the data revealed and to what it did *not* reveal.” ECF No. 26 at 5. Even if there has been a public disclosure, Relator contends, he is an “‘original source’—an individual ‘who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.’” *Id.* at 7 (quoting 31 U.S.C. § 3730(e)(4)(B)(2)). Finally, Relator agrees Rule 9(b) applies to his FCA claims, but contends the allegations in the Complaint satisfy the rule’s particularity requirements by alleging the time, place, and contents of the misrepresentations, as well as a pattern of conduct that would necessarily have led to the submission of false claims to the Government for payment. *Id.* at 8-10.

¹ Here, Relator recognizes the general prohibition against double recovery, which is designed to prevent a plaintiff from recovering twice for the same harms. *See, e.g., Weitz Co. v. Lexington Ins. Co.*, 786 F.3d 641, 648 (8th Cir. 2015) (“It is a well settled ‘equitable principle that the injured party is entitled to be made whole but not allowed a double recovery.’”) (quoting *Allied Mut. Ins. Co. v. Heiken*, 675 N.W.2d 820, 828 (Iowa 2004)); *Dopp v. HTP Corp.*, 947 F.2d 506, 517 (1st Cir. 1991) (“[T]he law abhors duplicative recoveries. That is to say, a plaintiff who is injured by reason of a defendant’s behavior is, for the most part, entitled to be made whole—not to be enriched.”).

Odom replied, contending for the first time that he is not the proper party to this action, and Relator has failed to join the proper parties, Hartsville Anesthesia Associates, P.A., and Advanced Pain Therapies, LLC. ECF No. 27 at 2. At a minimum, Odom argues, these entities are essential parties as all reimbursements would have been received by them and he was only their employee. Odom asserts Relator has formulated medical opinions without the necessary experience, knowledge, or qualifications, and is “nothing more than a data miner.” *Id.* at 3. Odom notes there are multiple obvious alternative explanations for his billing activity, including his participation in a clinical trial. Further, Odom disputes Relator is an original source and disputes the allegations in the Complaint meet Rule 9(b)’s particularity standard.

3. Supplemental Motion to Dismiss.

On September 14, 2020, Odom filed a supplemental motion to dismiss (Supplemental Motion to Dismiss) under Rule 12(b)(1) of the Federal Rules of Civil Procedure and the FCA’s government-action bar, 31 U.S.C. § 3730(e)(3). ECF No. 38. According to Odom, application of the government-action bar requires dismissal of Relator’s complaint for lack of subject matter jurisdiction because the Complaint does not extend beyond the boundaries of two current administrative proceedings against him and numerous previous administrative proceedings against other health care providers. *Id.* at 4. Relator responds the government-action bar does not apply because none of the administrative proceedings relied upon by Odom constitute a civil suit or administrative penalty proceeding as required to trigger the government-action bar. ECF No. 39 at 1. Further, Relator contends, “[e]ven if the administrative materials relied upon by [Odom] did constitute a civil suit or penalty proceeding (which they do not), they are not based on the same

allegations or transactions as in this case, and, therefore,” the government-action bar “does not apply.” *Id.* Odom replies the administrative proceedings currently pending against him constitute civil money penalty proceedings under the government-action bar, and the previous administrative proceedings against other health care providers support his position the nerve conduction studies he performed as alleged in the Complaint were medically necessary. *Id.* at 1, 5. Finally, Odom contends he is entitled to exhaust his administrative remedies prior to this court exercising jurisdiction over Relator’s FCA claims. *Id.* at 6-8.

B. Order of Analysis.

For reasons of logical analysis, this Order addresses the various grounds upon which Odom seeks dismissal in the following order: (1) subject-matter jurisdiction-Constitutional mootness; (2) the government-action bar, 31 U.S.C. § 3730(e)(3); (3) the public-disclosure bar, 31 U.S.C. § 3730(e)(4); (4) failure to satisfy the pleading standards of Rules 8(a)(2) and 9(b); and (5) administrative exhaustion.

II. Subject Matter Jurisdiction—Constitutional Mootness.

Article III of the United States Constitution grants federal courts the authority to adjudicate legal disputes only in the context of “Cases” or “Controversies.” U.S. Const. art. III, § 2. “A case becomes moot—and therefore no longer a ‘Case’ or ‘Controversy’ for purposes of Article III—‘when the issues presented are no longer “live” or the parties lack a legally cognizable interest in the outcome.’” *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quoting *Murphy v. Hunt*, 455 U.S. 478, 481 (1982) (*per curiam*) (some internal quotation marks omitted)). Notably, “as long as the parties have a concrete interest, however small, in the outcome of the litigation, the case is

not moot.” *Ellis v. Railway Clerks*, 466 U.S. 435, 442 (1984). *Accord Powell v. McCormack*, 395 U.S. 486, 497 (1969) (“Where one of the several issues presented becomes moot, the remaining live issues supply the constitutional requirement of a case or controversy.”). Thus, “[a] case becomes moot only when it is impossible for a court to grant any effectual relief whatever to the prevailing party.” *Knox v. Service Emps.*, 567 U.S. 298, 307 (2012) (internal quotation marks omitted). *Accord Church of Scientology of Ca. v. United States*, 506 U.S. 9, 12 (1992) (when court can no longer grant any effectual relief, case must be dismissed, even if on appeal).

Because mootness presents a question of subject matter jurisdiction, *Arizonans for Official English v. Arizona*, 520 U.S. 43, 66-67 (1997), a mootness challenge to a complaint is evaluated under Federal Rule of Civil Procedure 12(b)(1), *Simmons v. United Mortg. and Loan Inv., LLC*, 634 F.3d 754, 762 (4th Cir. 2011). Accordingly, the court may look beyond the pleadings and view any evidence submitted to determine whether a claim is moot. *See Williams v. United States*, 50 F.3d 299, 304 (4th Cir. 1995) (district court “may consider the evidence beyond the scope of the pleadings to resolve factual disputes concerning [subject matter] jurisdiction”).

With respect to each CPT Code at issue, this Order will lay out the facts relevant to Odom’s mootness argument, set forth the specifics of the parties’ opposing arguments, and then address those arguments.

A. CPT Code 64450 for Nerve Block Injections (claims for services in 2016 and 2017).

1. Facts.

The Complaint alleges Medicare paid Odom a total of \$476,715 for 14,541 claims he submitted under CPT Code 64450 for nerve block injections to a total of 94 patients (averaging

155 claims per patient) in 2016. ECF No. 1 at 9. The Complaint further alleges Medicare paid Odom a total of \$411,321 for 12,749 claims he submitted under the same code for nerve block injections to a total of 110 patients (averaging 116 claims per patient) in 2017. *Id.* According to the Complaint, “[i]f . . . Odom actually performed the number of procedures per patient that he claimed then he unnecessarily risked patient harm.” *Id.* at 10. Further, the Complaint alleges the claims Odom submitted under CPT Code 64450 “reflect a pattern in which patients risk excessive frequency for unnecessary and potentially risky injections.” *Id.* “For these reasons,” the Complaint alleges, “many or most of the claims submitted by Dr. Odom for CPT [Code] 64450 are false.” *Id.*

With respect to these claims (for 2016 and 2017), Odom contends the Complaint should be dismissed as moot because he “is currently facing recoupment for Medicare claims submitted under” CPT Code 64450 for nerve block injections he performed in 2016. ECF No. 18 at 9. As evidence, Odom has submitted a 503-page document, dated August 30, 2018, which lists both Odom and Hartsville Anesthesia Associates as “Appellant.” ECF No. 41-1 at 2-3. The document constitutes a Medicare appeal decision (the 2018 Appeal Decision), rendered by a Qualified Independent Contractor (“QIC”). This decision covers peripheral nerve injection services provided by Odom “in conjunction with Hartsville Anesthesia Associates” and billed under CPT

Code 64450, for dates of service covering the entirety of 2016, but none for 2017.² ECF No. 41-1 at 3.

a. Background leading to the 2018 Appeal Decision.

Palmetto Government Benefit Administrators, LLC (“PGBA”) is a Medicare administrative contractor (“MAC”). According to the CMS website, a MAC “is a private health care insurer who has been awarded a geographic jurisdiction to process Medicare” claims. <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC> (last visited Feb. 2, 2021). Notably, although MACs are authorized to review and pay Medicare claims and to provide related services such as Medicare-provider enrollment, MACs are not authorized to impose penalties on Medicare providers. 42 U.S.C. § 1395kk—1.

According to the 2018 Appeal Decision, PGBA initially paid the claims for 2016, but subsequently notified Odom of an extrapolated overpayment amount of \$445,825.05, based upon its post-payment review of a 486-claim sample involving medical records of 30 patients, ECF No. 41-1 at 2-3, 9, for the following primary reasons: (1) the documentation submitted did not meet

² Odom contends all of the Medicare services he performed were billed by Hartsville Anesthesia Associates, P.A. and Advanced Pain Therapies, LLC, ECF No. 25, and therefore, these entities are the proper parties in this action, not him. “At a minimum,” Odom argues, “these entities are essential parties as [he] was only an employee of these entities.” ECF No. 27 at 2. The court notes Odom has not filed a motion to dismiss the Complaint under Rule 12(b)(7) of the Federal Rules of Civil Procedure for failure to join these two entities as parties under Rule 19 of the Federal Rules of Civil Procedure. Unless necessary for clarity, this Order will refer only to Odom with respect to the underlying facts.

The court notes the 2018 Appeal Decision does not indicate whether Hartsville Anesthesia Associates is a Professional Association as represented by Odom before this court. ECF Nos. 25 at 3, 27 at 2.

medical necessity requirements per CMS guidelines; (2) the documentation submitted was altered; (3) “[t]he documentation submitted was for wrong patient, wrong date of service, or wrong documentation”; (4) no documentation was received as requested; or (5) the claim was billed in error, *id.* at 10-11.

Odom then submitted a redetermination request to PGBA, which resulted in PGBA fully upholding its prior decision. *Id.* at 3. PGBA’s primary reason for upholding the decision at the redetermination stage included the following: “Peripheral nerve blocks or injections for the treatment of diabetic peripheral neuropathy (chronic pain) are not covered. At this time, there is insufficient literature/scientific evidence to support the use of peripheral nerve blocks or injections for peripheral neuropathies caused by underlying systemic diseases.” *Id.* at 11.

Continuing to challenge the unfavorable decision, Odom filed a Medicare appeal. *Id.* at 2. Medicare contracted with C2C Innovative Solutions, Inc. (C2C), a QIC, to conduct a *de novo* review of the decision. *Id.* at 2-3. On appeal, Odom made six arguments. In his first argument, Odom argued PGBA’s “Redetermination Decision did not address [his] enrollment in a national study and the claims being submitted as being involved in the qualifying Clinical Trial Policy.” *Id.* at 11. C2C responded that its *de novo* reconsideration would cure this failure-to-address defect, and further stated:

While the services may have been rendered under a clinical trial, that alone does not determine coverage. The QIC reviews all services against Medicare rules and regulations, as well as accepted standards of medical practice. Therefore, the enrollment in a clinical trial alone does not automatically ensure services are covered.

Id. at 11. Odom’s remaining arguments focused on his position the claims should be covered because he performed the services during a clinical trial registered with the Medicare Clinical Trials Registry and the services were not investigational, but reasonable and medically necessary. *Id.* at 12-13. C2C rejected every argument. *Id.* at 12-13. In so rejecting, C2C notably responded: “Clinical Trials.gov is a resource provided by the U.S. National Library of Medicine. It is a registry site for clinical trials; however, listing a study does not mean it has been evaluated by the U.S. Federal Government. Appellant has provided no evidence demonstrating Medicare approval of this study.” *Id.* at 12. In the “Claim Review” section of the decision, C2C affirmed the denial of 100 claims for altered documentation, 10 claims for medical records sent for the wrong patient, wrong date of service, or lack of documentation, 40 claims for wrong documentation, and 48 claims for billing in error. *Id.* at 14-15. The remaining 4550 claims were denied as not medically necessary. *Id.* at 15.

In a letter dated August 30, 2018, Odom was notified “[t]he Appeal decision is UNFAVORABLE,” ECF No. 41-1 at 2, and he had sixty days from his receipt of the letter to appeal to an administrative law judge (ALJ). *Id.* at 2. According to Odom, he has noted an appeal of the 2018 Appeal Decision, which is currently pending (*i.e.*, awaiting a hearing date before an ALJ). ECF No. 38 at 4 (Odom’s Supplemental Motion to Dismiss, filed Sept. 14, 2020) (“The Medicare appeal initiated by Defendant challenging this recoupment resulted in a decision which is currently on appeal.”); ECF No. 40 at 4 (Odom’s Reply to Relator’s Opposition to Odom’s Supplemental Motion to Dismiss, filed Oct. 5, 2020) (stating hearing date not yet received).

2. Arguments.

Based upon the 2018 Appeal Decision with respect to the 14,541 claims he submitted under CPT Code 64450 for nerve block injections to a total of 94 patients in 2016, Odom argues **all** of Relator's allegations with respect to CPT Code 64450 (2016 and 2017) are moot "as Relator brings forth no new information which could aid the government in recouping additional money from [Odom] for services rendered under CPT [C]ode 64450." ECF No. 18 at 10. In response, Relator makes three arguments. First, Relator argues the 2018 Appeal Decision only pertains to claims submitted by Odom under CPT Code 64450 for services he performed **in 2016**, and therefore, cannot be considered to moot any claims Relator has with respect to claims submitted by Odom under CPT Code 64450 for services he performed **in 2017**. Second, Relator argues he seeks \$30,890 more in overpayment for claims submitted by Odom under CPT Code 64450 for services he performed in 2016 as compared to the amount sought by the Government for presumably the same claims, resulting in the 2018 Appeal Decision (Relator seeks \$476,715 as compared to the extrapolated amount sought by the Government of \$445,825.05). ECF Nos. 1 at 9, 41-1 at 3. Third, Relator notes his Complaint seeks penalties and damages under the FCA, which are not part of or at issue in the administrative-recoupment proceedings and therefore not mooted by such proceedings.

In response, Odom argues because the issue whether his claims for services under CPT Code 64450, performed in 2016, are determined to be medically necessary is still awaiting a hearing before an ALJ, and CMS retains the authority to assess penalties against him for retaining overpayments in bad faith "at all stages of the administrative process, . . . this court cannot determine whether the pending proceedings are 'penalty proceedings' until final agency action and

should, at a minimum, stay Plaintiff-Relator's claim until resolution of the pending administrative proceedings." ECF No. 40 at 2.

3. Analysis.

Relator's claims alleging Odom knowingly submitted or caused submission of false claims under CPT Code 64450 for services performed in 2016 and 2017 are not moot. Although Relator will not be able to recover for amounts found owing in pending administrative recoupment proceedings, issues remain with respect to penalties and damages under the FCA. Additionally, Relator's Complaint seeks recovery for overpayments Odom allegedly received for claims under CPT Code 64450 in 2017 and related penalties and alleged damages. *See Powell*, 395 U.S. at 497. Finally, the fact the Government, via CMS, retains the authority to assess penalties against Odom at a future date is not relevant to a mootness analysis, which turns upon whether an event previously rendered a pending claim moot.

B. CPT Code 76942 for "Ultrasonic guidance imaging supervision and interpretation for insertion of needle." (claims for services in 2014, 2015, 2016, and 2017)

1. Facts.

The Complaint alleges CPT Code 76942 is a code for ultrasound guidance imaging needed to help place needles deep within a patient at a site that is not otherwise visible. ECF No. 1 at 15. The Complaint alleges Medicare paid Odom a total of \$70,659 for 1,377 claims he submitted under CPT Code 76942 for ultrasound guidance imaging for 279 patients in 2014; \$7,525 for 171 claims for 99 patients in 2015; \$3,378 for 79 claims for 32 patients in 2016, and \$2,461 for 55 claims for 27 patients in 2017. *Id.* According to the Complaint, because so many of Odom's CPT Code

64450 injections were unnecessary, “Relator believes many or most of the claims [Odom] submitted for CPT [Code] 76492 claims are also false.” ECF No. 1 at 17. In other words, Relator’s theory of Odom’s liability for CPT Code 76492 is that ultrasound guidance provided in conjunction with a medically unnecessary CPT Code 64450 injection is also medically unnecessary.

2. Arguments.

Odom argues because Relator’s allegations regarding CPT Code 64450 are moot, Relator’s allegations regarding CPT Code 76492 are also moot. ECF No. 18 at 10. This is so, Odom argues, because Relator’s FCA claims pertaining to CPT Code 76492 rest entirely upon Relator’s incorrect “belie[f] many or most” of the claims Odom submitted for CPT Code 76492 are false because “so many of [his] CPT 64450 injections [were] not medically necessary” *Id.* The crux of Relator’s response is the 2018 Appeal Decision did not pertain to claims Odom submitted under CPT Code 76492, and therefore, that decision did not render moot Complaint allegations concerning those claims.

3. Analysis.

There is no basis to hold Relator’s allegations regarding CPT Code 76492 constitutionally moot. First, as just discussed, *see supra* Part II.A., Relator’s allegations regarding CPT Code 64450 are not moot. Second, the 2018 Appeal Decision did not address claims submitted by Odom under CPT Code 76492. Therefore, that decision cannot serve to moot any FCA claims based upon CPT Code 76492. Third, assuming *arguendo* the 2018 Appeal Decision did pertain to claims submitted by Odom under CPT Code 76492, Relator’s allegations with respect to claims submitted

by Odom under CPT Code 76492 cover years 2014 through 2017, not just year 2016, as is the case with the 2018 Appeal Decision. In short, Odom's contention the court should dismiss as moot Relator's FCA claims pertaining to CPT Code 76492 lacks merit.

C. CPT Code 95909 for Nerve Transmission Studies (claims for services in 2016 only).

1. Facts.

CPT Code 95909 is a code for nerve transmission studies. The Complaint alleges Medicare paid Odom a total of \$67,211 for 624 claims under CPT Code 95909 for nerve transmission studies on a total of 105 patients in 2016. ECF No. 1 at 14.

2. Arguments.

Odom contends Relator's allegations with respect to this code are moot because the Government has initiated several administrative recoupment actions against other physicians utilizing the Axon-II 250 Hz small pain fiber testing device to conduct nerve transmissions studies, and Relator's allegations fail to put the Government on any additional notice. ECF No. 18 at 10. In support, Odom cites three ALJ decisions and three QIC decisions in Medicare appeals. *Id.* at 10 n.7. After some back and forth, Odom submitted copies of these decisions, but all of the provider names are redacted. ECF No. 27 (attachments 1-6). Further, Odom relies on Exhibit 2 to his Supplemental Motion to Dismiss Relator's Complaint, which is a Medicare Appeal Decision rendered by a QIC, dated February 19, 2016 (the 2016 Appeal Decision), reiterating denial as medically unnecessary 472 claims submitted by "Hartsville Anesthesia Advanced Pain Therapies, LLC," ECF No. 38-2 at 2, under CPT Code 95904, for "Nerve conduction, amplitude and

latency/velocity study, each nerve; sensory,” ECF 38-2 at 6, (*i.e.*, sensory nerve conduction threshold testing) performed in 2009 and 2010. ECF No. 38-2 at 19. The identity of the person to whom the decision was addressed is redacted, and the decision does not state an overpayment amount. Citing the Federal Register, Odom claims, beginning January 1, 2013, CPT Code 95904 changed to the current CPT Code 95909. ECF No. 40 at 4.

In response, Relator points out the obvious. First, administrative decisions in cases involving other physicians cannot render claims against Odom under the FCA moot. Second, the 2016 Appeal Decision relates to a code and time period not at issue in the Complaint. And third, a copy of the same 2016 Appeal Decision, “was produced to Relator (stamped “confidential”),” which revealed the sole unredacted recipient was an Arkansas-based healthcare provider not a party to this litigation. ECF No. 39 at 3.

In response, Odom asserts the 2016 Appeal Decision concerns the medical necessity of nerve conduction studies billed by his practice for treatment rendered by him under then CPT Code 95904 (now CPT Code 95909) in years 2009 and 2010. ECF 40 at 4. Odom further asserts, “[t]his decision was not issued to a different healthcare provider but instead issued to [his] practices and mailed to [his] representative.” *Id.* The gist of Odom’s response is he should be allowed “the opportunity to obtain an agency decision before Plaintiff-Relator is allowed to duplicate the same process currently proceeding before the executive agency currently exercising its decision-making authority over the same subject matter.” *Id.* at 5. Odom does not explain how or why the 2016 Appeal Decision is still awaiting final agency action nearly five years later.

3. Analysis.

Relator's FCA claims pertaining to 624 claims Odom submitted under CPT Code 95909 for nerve transmission studies on a total of 105 patients in 2016 are not moot. Assuming *arguendo* the 2016 Appeal Decision covers claims submitted by Odom, the decision, which covers claims submitted in 2009 and 2010, cannot serve to moot claims for a different time period.

III. The Government-Action Bar, 31 U.S.C. § 3730(e)(3).

A. Introduction.

Odom seeks dismissal of the entire Complaint under Federal Rule of Civil Procedure 12(b)(1) and 31 U.S.C. § 3730(e)(3), which statutory provision provides “[i]n no event may a person bring an action under [31 U.S.C. § 3730(b)] which is based upon allegations or transactions which are the subject of a civil suit or administrative civil money penalty proceeding in which the Government is already a party.” 31 U.S.C. § 3730(e)(3). This statutory provision, commonly known as the government-action bar, serves the FCA’s widely recognized general purpose of encouraging whistleblowing while discouraging parasitic or opportunistic behavior. *United States ex rel. S. Praver & Co. v. Fleet Bank of Maine*, 24 F.3d 320, 326 (1st Cir. 1994); *Kaboom! The Explosion of Qui Tam False Claims Under the Health Reform Law*, 116 Penn. St. L. Rev. 77, 85-86 (2011).

B. Arguments.

Odom contends the two current administrative recoupment proceedings (for claims under CPT Code 64450 for services performed in 2016 and for claims under CPT Code 95904 for services performed in 2009 and 2010), constitute “administrative civil money penalty proceeding[s]” under the government-action bar because CMS could one day assess money

penalties against him based on such claims. Odom also contends the allegations in the Complaint do not extend beyond the boundaries of such proceedings. Under these circumstances, Odom posits, the government-action bar requires dismissal of Relator's entire Complaint.

The primary case upon which Odom relies is *Foundation For Fair Contracting, Ltd v. G & M Eastern Contracting & Double E, LLC*, 259 F. Supp. 2d 329 (D.N.J. 2003), a *qui tam* action preceded by a United States Department of Labor (DOL) investigation into alleged false claims. DOL completed its investigation a year after the relator's filing and resulted in the defendants paying back wages to the Government. *Id.* at 333-34. The district court dismissed relator's *qui tam* action for lack of subject matter jurisdiction, finding the DOL investigation constituted an "administrative civil money penalty proceeding" under the government-action bar, because although DOL chose to compromise and settle for back wages with no additional civil money penalty, it had the regulatory authority to do so. *Id.* at 339. The court held allowing the relator's *qui tam* action to proceed would "provide for a second recovery by another entity despite resolution of the [G]overnment's investigation into the very same transactions, in contravention of the statutory purpose." *Id.* at 337. *See also id.* at 339 (government-action bar applied because *qui tam* action sought to remedy fraud the Government had already investigated within its full regulatory authority, culminating in a resolution acceptable to the Government, based on the same set of underlying facts).

Relator makes several arguments in response. First, Relator argues the government-action bar is inapplicable because the administrative recoupment proceedings referenced by Odom are neither civil suits, nor civil money penalty proceedings. In this regard, Relator points out neither

PGBA nor C2C as a QIC possess the authority to impose any penalties, monetary or otherwise, upon Odom. On this basis, Relator distinguishes *Foundation*, 259 F. Supp. 2d 339, the case upon which Odom primarily relies. Second, Relator argues, assuming *arguendo* CPT Code 95909 is the more recent equivalent of CPT Code 95904, the administrative recoupment proceedings based upon CPT Code 95904 (resulting in the 2016 Appeal Decision) cover claims for an entirely different time period than the Complaint allegations regarding CPT Code 95909 (2009 through 2010 versus 2016), and therefore, on their face, cannot trigger the government-action bar. Third, Relator cites the problem with the identity of the sole unredacted recipient of the 2016 Appeal Decision as an Arkansas-based healthcare provider with no apparent connection to Odom. Fourth, Relator reiterates that administrative recoupment proceedings for claims submitted under CPT Code 64450 for services Odom performed in 2016 do not cover claims for services Odom performed in 2017, nor do they cover allegations of fraud for claims for services Odom performed in 2016 and 2017.

C. Analysis.

The law is not settled whether the government-action bar implicates the court's subject matter jurisdiction, constitutes an affirmative defense, or merely results in failure to state a claim upon which relief can be granted. *See, e.g., United States ex rel. Absher v. Momence Meadows Nursing Ctr. Inc.*, 764 F.3d 699, 706 (7th Cir. 2014) (observing "it is not clear that § 3730(e)(3) imposes a true jurisdictional limitation"). However, the court need not decide whether the government-action bar implicates the court's subject matter jurisdiction because the outcome is the same regardless.

Properly viewed, the only actual overlap between the two administrative recoupment proceedings relied upon by Odom and the allegations contained in the Complaint pertains to one of the three CPT Codes at issue (*i.e.*, CPT Code 64450) and to one of the two years alleged as to that CPT Code (*i.e.*, 2016). Thus, properly framed, the issue here is whether the existence of the allegedly still pending administrative recoupment proceedings against Odom for medical services he provided under CPT Code 64450 in 2016 requires dismissal of the Complaint pursuant to the government-action bar.³ The answer is no.

First, the administrative recoupment proceedings against Odom for medical services provided under CPT Code 64450 in 2016 constitute neither a civil suit nor an administrative civil money penalty proceeding within the plain language of the government-action bar. *See United States ex rel. Int'l Broth. of Elec. Workers, Local Union No. 98 v. Fairfield Co.*, 2013 WL 3327505, at *12 (E.D. Penn. July 2, 2013) (rejecting argument government-action bar applied to *qui tam* action alleging fraud claim because the Department of Labor had conducted an audit, but did not seek a penalty); *United States ex rel. Johnson v. Shell Oil Co.*, 26 F. Supp. 2d 923, 928 (E.D. Tex. 1998) (denying motion to dismiss FCA claim because the federal Mineral Management Service audit did not seek a penalty). Relator is correct neither PGBA nor C2C as a QIC possess authority to impose any penalties, monetary or otherwise, upon Odom. Additionally, Odom makes no contention administrative recoupment proceedings pertaining to medical services he provided

³ Odom has not submitted any documentation evidencing the 2018 Appeal Decision is still pending in ongoing administrative proceedings.

under CPT Code 64450 in 2016 seek any civil monetary penalty or that CMS has intervened to impose any sort of civil monetary penalty. Odom offers nothing but speculation CMS may do so one day. *United States ex rel. McDermott v. Genentech, Inc.*, 2006 WL 3741920, at *7 (D. Maine Dec. 14, 2006) (magistrate judge R & R) (recommending government-action bar did not apply to require dismissal of FCA claim based on a Justice Department investigatory subpoena, because “there is nothing but ... speculation to suggest that the government will obtain redress through its investigation”). The instant case is thus wholly distinguishable from *Foundation*, 259 F. Supp. 2d 339, the case upon which Odom primarily relies, in which the Government had used its full regulatory power to investigate the defendant.

The second major reason the government-action bar does not apply to bar the FCA claims alleged in the Complaint is the administrative recoupment proceedings are not grounded on allegations of fraud of any kind. *See Praver*, 24 F.3d at 329 (collection case by Government against same defendants as *qui tam* action alleging fraud did not trigger government-action bar because collection case did not allege fraud); *United States ex rel. Herndon v. Appalachian Reg’l Cmty. Head Start*, 2009 WL 249645, at *3 (W.D. Va. 2009) (United States Department of Health and Human Services’ investigation seeking repayment of disallowed costs from operator of Head Start Program did not trigger government-action bar against *qui tam* claim alleging same operator of Head Start Program fraudulently made expenditures with knowledge such expenditures violated Head Start regulations, because the administrative investigation and the *qui tam* claim did not share a host/parasitic relationship). While federal law provides the Secretary of Health and Human Services (the Secretary) with authority under the Medicare Integrity Program to enter into contracts

with entities to conduct fraud review of claims submitted by Medicare providers, *see* 42 U.S.C. § 1395ddd(a)-(b), Odom neither contends the Secretary has entered into such a contract with PGBA or C2C as the QIC nor contends the administrative recoupment proceedings with respect to claims submitted under CPT Code 64450 for medical services provided in 2016 involve any sort of fraud review. To sum up, the instant *qui tam* action seeks recovery for fraud for which the Government has not yet sought to recover. Accordingly, the government-action bar does not support dismissal of Relator’s Complaint.

IV. Public Disclosure Bar, 31 U.S.C. § 3730(e)(4).

A. Introduction.

In general, 31 U.S.C. § 3730(e)(4), commonly known as the public-disclosure bar, prohibits FCA actions based on allegations that have already entered the public domain, unless the relator qualifies as an original source. Congress amended the FCA, effective March 23, 2010, and revised several parts of the public-disclosure bar. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, Title X, § 10104(j)(2), 124 Stat. 119, 901-02 (2010). The 2010 amended version, applicable in the instant case, “is a ground[] for dismissal—effectively, an affirmative defense—rather than a jurisdictional bar.”⁴ *United States ex rel. Beauchamp v. Academi Training Center*, 816 F.3d 37, 40 (4th Cir. 2016). The applicable version provides:

⁴ Prior to the 2010 amendments, the public-disclosure bar created a ground for dismissal under Rule 12(b)(1) of the Federal Rules of Civil Procedure. *See Rockwell Int’l Corp. v. United States*, 549 U.S. 457, 467-68 (2007); *United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 916 (4th Cir. 2013). Congress also made a housekeeping amendment to the public disclosure bar, effective July 22, 2010, which is not relevant here.

The court shall dismiss an action or claim under this section, unless opposed by the Government, **if substantially the same allegations or transactions** as alleged in the action or claim were publicly disclosed—

- (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
- (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
- (iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (2010) (emphasis added).

For purposes of the public-disclosure bar,

“‘original source’ means an individual who either (1) prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

Id. § 3730(e)(4)(B). Notably, since its amendment in 2010, the public-disclosure bar no longer requires the relator to have actually derived his knowledge of the fraud from the public disclosure. *Beauchamp*, 816 F.3d at 40. Rather, the public-disclosure bar “‘applies if substantially the same allegations or transactions were publicly disclosed.’” *Id.* (quoting *May*, 737 F.3d at 917).

B. Arguments.

First, Odom seeks to invoke the public-disclosure bar based upon the two allegedly current administrative recoupment proceedings against him (for claims under CPT Code 64450 for services performed in 2016 and for claims under CPT Code 95904 for services performed in 2009

and 2010). ECF No. 18 at 7. Odom then contends Relator does not qualify for the original source exception because he pleads no new material information which is outside the existing public domain. *Id.* at 13. Rather, Odom contends, Relator “only regurgitates CMS data and [Local Coverage Determination] content already published and publicly available in the administrative decisions rendered and [Odom’s] online study results.” *Id.* at 15. Odom also contends Relator’s allegations with respect to CPT Code 95909 were publicly disclosed in the details of his clinical trial, as well as the 2016 results, which explain that he “utilized the Axon-II to conduct small pain fiber NCSs to objectively confirm impairment of enrolled patients’ lower extremities to allow admittance into the study, with follow up NCSs conducted to document objective response of the nerve fibers.” *Id.* With respect to CPT Code 76492, Odom contends the public-disclosure bar applies because Relator “simply repeats publicly available CMS statistical data and drafts a CMS chart outlining the types of providers and how many times each type is billed under” CPT Code 76492. *Id.* at 16. Finally, Odom relies on copies of three ALJ decisions and three QIC decisions in Medicare appeals, ECF 18 at 10 n.7, in which all of the provider names are redacted. ECF No. 27 (attachments 1-6). According to Odom, these decisions stem from administrative actions seeking to recoup money from other physicians utilizing the Axon-II 250 Hz small pain fiber testing device to conduct nerve transmission studies, and Relator’s allegations fail to put the government on any additional notice. ECF No. 18 at 10.

After relying on this alleged publicly available information to invoke the public-disclosure bar, Odom makes clear he “does not argue that Relator’s action is barred because the ‘allegations or transactions’ are contained in CMS data.” ECF No. 27 at 6. Instead, he argues, “there is clear

evidence demonstrating that the government has already been put on notice of these allegations or transactions and has issued final agency decisions approving of the same” *Id.* The “clear evidence” Odom cites in support of this argument is an ALJ decision (following a telephonic hearing), dated April 13, 2016, from the Office of Medicare Hearings and Appeals, Western Field Office, Irvine, California. ECF No. 27-1. The medical provider’s name and the appellant-patient’s name are redacted throughout the decision. At most, this decision stands for: (1) the same study under which Odom contends he billed the three CPT Codes at issue in the Complaint in the instant case, *i.e.*, Study of Neurological Ischemia Lower Extremity Pain and Swelling (NCT01979367), was in fact registered in the Medicare clinical trials registry with a start date of March 2012, *id.* at 8, and (2) the claims submitted for injections of anesthetics and small pain fiber testing under such clinical trial qualified as “routine costs associated with the qualifying clinical trial and involved services approved by the FDA for ischemic disorders and pain,” *id.* at 9. In the “Conclusions of Law” section of the ALJ’s April 13, 2016 decision, the ALJ states: “Numerous procedure codes billed by the Provider on numerous dates of service are eligible for Medicare coverage as routine costs of a qualifying clinical trial as noted in the Attachment. The Provider is entitled to Medicare payment in accordance with the Attachment.” *Id.* at 9. The ALJ decision itself does not list any CPT Codes, and Odom did not provide the court with the referenced “Attachment” in support of his Initial Motion to Dismiss.

In response, Relator first points out Odom’s assertion of the public-disclosure bar as an affirmative defense exceeds the confines of a Rule 12(b)(6) motion because Odom relies on documents not integral to or explicitly relied upon in the Complaint. ECF No. 26 at 2. Second,

assuming *arguendo* the court can consider those documents, Relator contends none of the documents relied upon by Odom qualify as public disclosures under the public-disclosure bar. *Id.* at 3-4. Third, Relator contends Odom heavily relies upon pre-2010 cases interpreting the pre-2010 public-disclosure bar and, worse, relies upon the pre-1986 version of § 3730(e)(4), which contained a defendant-favorable governmental-knowledge bar. *May*, 811 F.3d at 642 n.5 (recognizing, by eliminating the government-knowledge bar, Congress intended the 1986 amendments to § 3730(e)(4) to increase the number of *qui tam* actions). Fourth and finally, Relator, in effect, argues the public-disclosure bar does not apply on its face because, assuming *arguendo*, the court may consider the documents upon which Odom relies, none contain substantially the same allegations or transactions of fraud as alleged in the Complaint.

C. Analysis.

Odom has not carried his burden at the Rule 12(b)(6) stage of successfully establishing the public-disclosure bar as an affirmative defense. With limited exceptions, a court may not consider matters beyond the allegations in a complaint when considering the merits of a Rule 12(b)(6) motion. *United States ex rel. Grant v. United Airlines, Inc.*, 912 F.3d 190, 196 (4th Cir. 2018); *E.I. du Pont de Nemours & Co. v. Kolon Indus. Inc.*, 637 F.3d 435, 449 (4th Cir. 2011); *American Chiropractic v. Trigon Healthcare*, 367 F.3d 212, 234 (4th Cir. 2004). The court's focus on the allegations in the four corners of the complaint in ruling on a motion to dismiss for failure to state a claim upon which relief may be granted derives from the purpose of a motion under Rule 12(b)(6) "to test the legal adequacy of the complaint, and not to address the merits of any affirmative defenses." *Richmond, Fredericksburg & Potomac R.R. Co. v. Forst*, 4 F.3d 244,

250 (4th Cir. 1993). *See also Edwards v. City of Goldsboro*, 178 F.3d 231, 243-44 (4th Cir. 1999) (courts generally do not “resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses” through a Rule 12(b)(6) motion) (internal quotation marks omitted).

One exception to the general rule a court may not consider matters beyond the allegations of a complaint when considering the merits of a Rule 12(b)(6) motion is when a court takes judicial notice of an adjudicative fact not subject to reasonable dispute because it is either generally known within the trial court’s territorial jurisdiction or can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned. Fed. R. Evid. 201(a)-(b). “Under this exception, courts may consider ‘relevant facts obtained from the public record,’ so long as these facts are construed in the light most favorable to the plaintiff along with the well-pleaded allegations of the complaint.” *Clatterbuck v. City of Charlottesville*, 708 F.3d 549, 557 (4th Cir. 2013) (quoting *B.H. Papasan v. Allain*, 478 U.S. 265, 283 (1986)).

Odom does not address the constraints Rule 12(b)(6) imposes upon the court’s consideration of the extrinsic documents he submitted and relies upon in support of his motion to dismiss the Complaint by invoking the public-disclosure bar. Indeed, he never comes to grips with the fact the public-disclosure bar is in the nature of an affirmative defense. Rather, generously construing Odom’s arguments, Odom asks the court to look at all of the extrinsic documents he has submitted and the results of the clinical trial study in which he participated in 2016 and 2017 and take judicial notice as an adjudicative fact that substantially the same allegations of fraud or transactions giving rise to an inference of fraud as alleged in the Complaint were publicly disclosed in a combination of Federal administrative hearings in which the Government or its agent is or was

a party or in a Federal “report, hearing, audit, or investigation” 31 U.S.C. § 3730(e)(4)(A). Odom’s argument requires the court to view his submitted evidence in the light most favorable to him and make inferences in his favor, which is plainly against the limited scope of Federal Rule of Evidence 201. For these reasons, Odom’s attempt to invoke the public-disclosure bar at the pleading stage of the litigation is simply a bridge too far. Accordingly, the FCA’s public-disclosure bar does not support dismissal of Relator’s Complaint at the pleading stage, and Odom’s Initial Motion to Dismiss based on the public-disclosure bar is denied without prejudice to his right to seek dismissal on the same ground in a motion for summary judgment.

V. Sufficiency of the Pleading under Rules 8(a)(2) and 9(b).

A. Introduction

Rule 8(a)(2) requires “a short and plain statement of the claim showing that the pleader is entitled to relief,” Fed. R. Civ. P. 8(a)(2), which requirement the Supreme Court has interpreted as requiring a complaint to include enough facts for a claim to be “plausible on its face,” *Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007), and thereby “raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact),” *id.* at 555 (internal citations omitted). Rule 9(b) provides that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b).

In Count I of the Complaint, Relator alleges Odom knowingly presented or caused to be presented false or fraudulent claims for payment or approval by the Government under the

Medicare program in violation of 31 U.S.C. § 3729(a)(1)(A), and the Government has “paid said claims and has sustained damages because of these acts by” Odom. ECF No. 1 at 17. In Count II, Relator alleges Odom “knowingly made, used or caused to be made, or used false records or statements material to a false or fraudulent claim” for payment or approval by the Government under the Medicare program in violation of 31 U.S.C. § 3729(a)(1)(B), and the Government has “paid said claims and has sustained damages because of these acts by” Odom. *Id.* As fraud claims under the FCA, Relator’s claims in Counts I and II must satisfy Rule 9(b)’s heightened pleading standard. *Grant*, 912 F.3d at 196. As the Fourth Circuit has recognized, “Rule 9(b)’s purposes of providing defendants notice of their alleged misconduct, preventing frivolous suits, and eliminating fraud actions in which all the facts are learned after discovery apply with special force to FCA claims and the accompanying presentment requirement.” *Id.* at 197.

Notably, “in order for a false statement to be actionable under either subsection of the FCA, it must be made as part of a false or fraudulent claim,” presented to the Government. *Grant*, 912 F.3d at 196. Fourth Circuit case law recognizes two alternative ways to adequately plead presentment under Rule 9(b): (1) to allege specific false or fraudulent claims were actually presented to the Government for payment; or (2) to allege a pattern of conduct that would necessarily have led to the submission of false or fraudulent claims presented to the Government for payment. *See id.* at 197. The first way requires a plaintiff, at a minimum, to “describe the ‘time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.’” *United States ex rel. Wilson v. Kellogg, Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (quoting *Harrison v. Westinghouse*

Savannah River Co., 176 F.3d 776, 786 (4th Cir. 1999)). And generally, “[a] court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts.” *Harrison*, 176 F.3d at 784.

B. Arguments

Here, Odom contends Relator fails to plead his allegations of fraud with sufficient particularity to satisfy Rule 9(b) and fails to allege facts, if accepted as true, which state a claim to relief that is plausible on its face as required by Rule 8(a)(2). In the main, Odom argues instead of Relator supporting his allegations of fraud with facts or information pertaining to Odom’s medical practice, Relator only provides conclusory reasons he thinks the Medicare claims at issue in the Complaint are false or fraudulent. Therefore, Odom asserts, the Complaint should be dismissed in its entirety under Rule 12(b)(6) for failure to state a claim upon which relief can be granted. In response, Relator contends the Complaint alleges a pattern of conduct that would necessarily have led to Odom’s submission of false or fraudulent claims to the Government for payment under the Medicare program, which is a permissible way to plead false or fraudulent presentment. *Grant*, 912 F.3d at 197. Odom concedes false or fraudulent presentment can be adequately plead by alleging a pattern of conduct that necessarily would have led to a defendant’s knowing submissions of false claims to the Government but argues the Complaint does not adequately allege such a pattern of conduct, and thus, Relator was required to allege with particularity specific false claims were actually presented to the government for payment. *See United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013)

(holding when defendant's actions, as alleged and as reasonably inferred from allegations in complaint, "*could* have led, but *need not necessarily* have led," to submission of false claims to Government, relator must allege with particularity specific false claims were actually presented to Government for payment).

C. Analysis.

Here, in general, the Complaint alleges as a part of every Medicare claim Odom submitted for reimbursement, he certified: (1) the services claimed were medically indicated and necessary for the health of the patient; (2) the services were personally furnished by him or were furnished incident to his professional service by an employee under his immediate supervision; and (3) the claims were accurate, complete, and truthful. ECF No. 1 at 4-5.

CPT Code 64450

With respect to CPT Code 64450 "Injection of anesthetic agent, other peripheral nerve or branch," the Complaint alleges Odom submitted 14,541 claims for services he performed in 2016 (averaging 155 claims per patient), for a total cost of \$476,715 and 12,749 claims for services he performed in 2017 (averaging 116 claims per patient), for a total cost of \$411,321, compared to the nationwide mean of 2.3 claims per patient. *Id.* at 9. The Complaint further alleges, "[i]n 2017, . . . Odom claimed [CPT] Code 64450 *more often than any doctor submitting claims under Medicare Part B.*" *Id.* The Complaint also alleges the risks of harm to a patient receiving a nerve block injection include temporary or permanent nerve damage, allergic reactions, and/or system toxicity. *Id.* at 8-9. Then the Complaint alleges the following (in ¶¶ 37-40) as the reasons

supporting Relator's allegation "that many or most [of] the claims submitted by Dr. Odom for CPT [Code] 64450 are false." *Id.* at 10.

C. Claims driven by financial considerations.

37. Relator's experience and investigation show that patients who seek assistance with pain know their symptoms, but they do not specifically seek treatment by CPT [Code] 64450 "injection of anesthetic agent, other peripheral nerve or branch."

38. With respect to the CPT [Code] 64450's customary practices and standards of care in South Carolina, Relator's investigation [(as a physician Board Certified in General Surgery-Hand Surgery)] revealed there was no "cluster" of symptoms or diagnoses that would indicate Defendant Odom's volume of repeat procedures are medically reasonable or necessary.

39. Relator's investigation has determined that Defendant Odom's reputation in the professional community would not have brought about referrals of patients with special needs requiring such unusual treatment.

40. If Defendant Odom actually performed the number of procedures per patient that he claimed then he unnecessarily risked patient harm. The CPT [C]ode 64450 claims Dr. Odom submitted to Medicare reflect a pattern in which patients risk excessive frequency for unnecessary and potentially risky injections.

ECF 1 at 10.

Odom argues all of Relator's allegations regarding CPT Code 64450 have an obvious alternative explanation, *i.e.*, his participation as a Principal Investigator in National Clinical Trial No. 01979367. In support, Odom cites two websites. ECF No. 18 at n.2. The first website lists Odom as a Principal Investigator in National Clinical Trial No. 01979367 and sets forth the "Physician Clinical Trial Policy" of the study. https://clinicaltrials.gov/ct2/history/NCT01979367?V_26=View#StudyPageTop (last visited Feb. 1, 2021). The second website contains a letter from Odom to the Board of the American Association of Sensory

Electrodiagnostic Medicine (AASEM), dated January 18, 2018, and purporting to be a 2017 Summary of the clinical trial results of National Clinical Trial No. 01979367. The introduction section states the trial is “powered according to the Primary Objective of demonstrating the non-inferiority of the devices in question (Axon II 250 Hz small pain fiber (spf) testing device, Anodyne/MIRE, TENS, NBPM . . .). If non-inferiority is demonstrated via positive responses to the Trial interventions, superiority of testing devices and therapeutic interventions can be assessed secondarily.” https://cdn.shopify.com/s/files/1/0915/1318/files/odom_17_sum.pdf?16450283569176905393 (last visited Feb. 1, 2021).

The difficulty with Odom’s reliance on a “Clinical Trial” defense, is that it is just that, a defense. He seeks to rely on documents not properly before the court at the Rule 12(b)(6) stage. Moreover, the documents on which he relies, while indicating Odom reported involvement in a clinical trial in 2017, fail to support his position the claims at issue here were covered by Medicare. *See* Unfavorable Appeal Decision by QIC dated Aug. 30, 2018, ECF No. 41-1 (noting the following: (1) Enrollment in a clinical trial alone does not automatically ensure services are covered; (2) Odom has provided no evidence demonstrating Medicare approval of this study; (3) The study cited by Odom was for the use of the Anodyne device and the services at issue are unrelated to his device; (4) A provider will be held liable for non-covered services if it is determined he had actual knowledge of a non-covered service or could reasonably have been expected to have knowledge. Providers are expected to have knowledge of the Medicare regulations regarding medical necessity of services they are providing; (5) 198 claim lines at issue were denied for altered documentation (100), records for wrong patient, wrong date of service,

lack of documentation (10), wrong documentation (40), and billed in error (48); (6) 4550 claim lines were denied as not medically necessary; and (7) The services were not found to be reasonable and necessary in the treatment of patients.).

Relator has adequately plead fraud with particularity under Rule 9(b) by alleging a pattern of conduct that would have necessarily led to Odom submitting false claims to the Government under CPT Code 64450 for years 2016 and 2017. First, Odom does not dispute he submitted the claims under CPT Code 64450 for nerve-block injections he allegedly gave patients in years 2016 and 2017 as alleged in the Complaint. The Complaint also alleges the amounts the Government paid Odom on the claims. Thus, this is not a case like *Grant* where the defendant lacks sufficient notice regarding whether or how any statement containing a false claim was presented to or paid by the Government and how or even whether the Government paid the defendant. *Grant*, 912 F.3d at 198-200 (affirming dismissal of relator's FCA claims under § 3729(a)(1)(A)-(B) in case where, although relator attempted to allege pattern of conduct that would necessarily have led to a false claim being submitted to the Government, the complaint lacked specific allegations as to whether or how any statement containing a false claim was presented to or paid for by the Government or how or even whether the Government paid defendant for the services). Odom also does not dispute the allegations putting his number of claims per patient per year at an enormously high rate compared to the mean of patients across the country. Rather, Odom only disputes Relator's allegation he knowingly submitted these claims falsely or knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim, and his only explanation is his participation in the clinical study. Unfortunately for Odom, Rule 9(b) allows

Relator to aver Odom's knowledge of the falsity of his claims generally. Moreover, at this stage of the game, there are no adjudicative facts of which the court can take judicial notice to nullify Relator's allegations.

CPT Code 95909

The same reasoning applies to Odom's claims submitted under CPT Code 95909 for 624 nerve transmission studies he allegedly performed in 2016 on a total of 105 patients at a total reimbursement cost of \$67,211, claiming on average six studies per patient compared to the national average of only one study per patient. *Id.* at 1 at 13. The Complaint alleges, based upon Relator's knowledge and experience, the high level of repetitions per patient "indicate the initial service was performed incorrectly (and thus a false claim), or that the first or the following services were not medically necessary." *Id.* at ¶ 51. The Complaint also alleges "[i]n Relator's experience and professional opinion, it is both implausible and beyond the standards of care that 105 patients arrived in [Odom's] office, all of whom required 5 to 6 studies, none more and none less, and that it was necessary to have patients return again and again to repeat the diagnostic, and that this was 'reasonable and necessary for the diagnosis' and that such studies were made in accordance with accepted standards of medical practice for the treatment of the patient's conditions, and not simply to increase the Defendant's profits." *Id.* at 14-15 ¶ 55. Given these allegations and the fact Relator is allowed to aver Odom's knowledge of the falsity of these claims generally, the Complaint adequately pleads under Rule 9(b) with respect to the claims Odom submitted under CPT Code 95909 by alleging a pattern of conduct that would have necessarily led to Odom submitting false claims to the Government. *Grant*, 912 F.3d at 197. The bottom line is the allegations in the

Complaint are sufficient to put Odom on notice of the particular circumstances for which he will need to prepare a defense, which is the purpose of Rule 9(b)'s requirements to plead fraud with particularity. *Harrison*, 176 F.3d at 784.

CPT Code 76492 (years 2014 – 2017)

The same reasoning applies to Odom's claims submitted under CPT Code 76492 for ultrasonic guidance imaging in year 2014. The Complaint adequately alleges a pattern of unnecessary ultrasonic guidance imaging when Odom submitted 1,377 claims under CPT Code 76492 for 2014 for a total reimbursement cost of \$70,659, averaging 4.9 claims per patient, but only submitted the same claim 171 times the following year (2015) averaging 1.7 claims per patient. ECF No. 1 at 15 ¶ 56. The Complaint also alleges because so many of Odom's CPT Code 64450 injections are not medically necessary, many or most of the claims Odom submitted for CPT 76492 to provide imaging guidance for such injections are also false. *Id.* at 16 ¶ 60. In support of this conclusion, the Complaint alleges "[t]he use of ultrasound guidance in conjunction with non-covered CPT 64450 injections (or any unnecessary injection) would also be considered not medically necessary." *Id.* at 16 ¶ 59. The Complaint then immediately cites Local Coverage Determination L35333 (unnecessary nerve blocks cannot justify unnecessary guidance). Along with the fact the Complaint can allege the scienter element generally, these allegations sufficiently put Odom on notice of the particular circumstances for which he will have to prepare a defense at trial. *Harrison*, 176 F.3d at 784.

Having so concluded with respect to the claims Odom submitted under CPT Code 76492 for services he provided in 2014, the same pattern of fraud does not hold up for years 2015, 2016,

or 2017. Compared to 2014, Odom only submitted 171 claims under 76492 for services he provided in 2015 for a total reimbursement cost of \$7,525, 79 claims in 2016 for a total reimbursement cost of \$3,378, and 55 claims in 2017 for a total reimbursement cost of \$2,461. ECF No. 1 at 15. Moreover, the Complaint also alleges there is nothing inherently fraudulent about a pain management doctor claiming CPT Code 76492. ECF. No.1 at 15 ¶ 59. The Complaint also acknowledges “[b]ecause ultrasonic guidance is required to help place needles deep in a body, it is typically claimed by anesthesiologists,” and Odom is a Board Certified anesthesiologist. *Id.*

In conclusion, with the exception just noted (for claims under CPT Code 76492 for years 2015, 2016, and 2017), the court finds dismissal under Rule 12(b)(6) for failure to meet the pleading requirements of Rules (8)(a)(2) and (9)(b) is not warranted. *See United States ex rel. Tucker v. Christus Health*, 2012 WL 5351212 (S.D. Tex. Oct. 23, 2012) (concluding relator satisfied Rule 9(b) by describing manner in which Medicare billing was false and/or fraudulent, specifying time period during which false claims were submitted to Medicare, providing specific examples of each category of fraudulent billing, and explaining defendants received millions of dollars thereby). The court grants Rule 12(b)(6) dismissal of Counts I and II for failure to meet the pleading requirements of Rules (8)(a)(2) and (9)(b) only to the extent such counts allege violation of the FCA for claims under CPT Code 76492 for years 2015, 2016, and 2017.⁵

⁵ Because the court finds the allegations in the Complaint for claims under CPT Code 76492 for years 2015, 2016, and 2017 are not clearly frivolous, the court denies Odom’s request for attorneys’ fees and costs as a prevailing defendant in this regard. *See* 31 U.S.C. § 3730(d)(4) (providing court may award reasonable attorneys’ fees and costs to prevailing defendant in FCA Footnote Continued . . .

VI. Administrative Exhaustion.

A. Introduction/Arguments.

In Odom’s Reply to Relator’s Opposition to his Supplemental Motion to Dismiss, Odom contends his medical practice is entitled to exhaust its administrative remedies prior to the court exercising jurisdiction over the merits of any portion of Relator’s claims in the Complaint. ECF No. 40 at 6-8. Odom contends 42 U.S.C. § 405(g)-(h), made applicable to Medicare claims by 42 U.S.C. § 1395ff(b)(1)(A), provides for exclusive judicial review of a final decision by the Secretary denying a Medicare provider’s claim for reimbursement of medical treatment he provided under the Medicare program. This means, Odom argues, if final agency action regarding either or both of the pending administrative recoupment proceedings results in decisions in his favor, the same medical services at issue in the Complaint will have been determined to be reasonable and medically necessary by the executive administrative agency with jurisdiction over said claims. ECF No. 40 at 7. Odom goes on to argue, in the event final agency action continues to be adverse, his practice will be able to seek judicial review, thus creating a conflict of jurisdiction. *Id.* at 8. “Therefore,” Odom concludes, “exercising jurisdiction over the claims in this matter is at best premature.” *Id.*

Relator has not had the opportunity to directly respond to these arguments because Odom raised them for the first time in his Reply to Relator’s Opposition to his Supplemental Motion to

action by relator in which the Government does not proceed if court finds relator’s claim “was clearly frivolous . . .”).

Dismiss. However, in Relator's Opposition to Odom's Supplemental Motion to Dismiss, ECF No. 39, Relator pointedly states Odom "failed to produce documents showing alleged pending appeals even though his Motion to Dismiss references pending appeals," *id.* at 2.

B. Analysis.

For several reasons, Odom is not entitled to administrative exhaustion before Relator can proceed with litigation on the Complaint. First, presuming the court can take judicial notice of documents establishing the administrative recoupment proceedings with respect to the 2016 Appeal Decision and the 2018 Appeal Decision are ongoing as an adjudicative fact under Federal Rule of Evidence 201, Odom's failure to submit such documentation is fatal to his exhaustion claim. Second, because Odom raised his administrative exhaustion claim for the first time in his Reply to Relator's Response to his Supplemental (*i.e.*, second) Motion to Dismiss, the claim comes far too late in the day to be considered. *See Clawson v. FedEx Ground Package Sys., Inc.*, 451 F. Supp. 2d 731, 734 (D. Md. 2006) (observing general rule in federal courts is argument raised for first time in reply brief or memoranda will not be considered). *Cf. United States v. Brooks*, 524 F.3d 549, 556 & n.11 (4th Cir. 2008) (deeming claim raised for first time in reply brief abandoned); *Yousefi v. INS*, 260 F.3d 318, 326 (4th Cir. 2001) (concluding petitioner abandoned argument on appeal raised for first time in reply brief by failing to raise it in opening brief). Third, neither the 2016 nor 2018 Appeal Decision entail any sort of fraud review, and thus, even though one year of claims under one code (CPT Code 64450 in 2016) overlaps with the claims at issue in the Complaint, no allegations of fraud overlap. In sum, Odom's claim to administrative exhaustion before the instant action can go forward fails.

VII. Conclusion

In conclusion, for the reasons set forth above, the court denies Odom's Initial Motion to Dismiss, ECF No. 18, based upon Constitutional mootness, the public-disclosure bar, and Rules 8(a)(2) and 9(b), with the exception of Relator's FCA claims relating to CPT Code 76492 for years 2015, 2016, and 2017, which are dismissed without prejudice. Furthermore, the court denies in full Odom's Supplemental Motion to Dismiss. ECF No. 38. Accordingly, Odom's request for attorneys' fees and costs is denied.

The Clerk of Court has been directed to enter a revised scheduling order.

IT IS SO ORDERED.

s/Cameron McGowan Currie
CAMERON MCGOWAN CURRIE
Senior United States District Judge

Columbia, South Carolina
February 2, 2021